

## **REMARKS**

The Office Action of March 26, 2003 has been thoroughly considered. In response thereto, Applicants have amended the application as requested above and offer the following rebuttal comments.

### **The Specification Rejection Concerning the Sequence Listing Information (Paragraph 1 of the Office Action)**

In the Office Action, the Examiner rejected the specification on the grounds that the sequence identified in Figure 4 (and the description thereto) failed to reference the sequence by SEQ ID NO. However, please note that the sequence shown in Figure 4 is from position 1 to position 52 of SEQ ID NO: 2. In order to clarify this, the specification has been amended to directly state this relationship.

In view of this amendment, the Examiner's previous rejection of the specification is believed to have been surpassed. Withdrawal of this rejection is respectfully requested.

### **Claim Rejection – 35 U.S.C. § 101 (Paragraphs 2-2 of the Office Action)**

In view of the 35 U.S.C. § 101 rejections, claims 1-12 and 14 have been cancelled without prejudice and claim 13 has been amended to include "comprising administering" instead of "using". Additionally, new claims 15-34 have been added. It is respectfully submitted that the amended and new claims overcome the Examiner's previous 35 U.S.C. § 101 rejections.

### **Claims Rejection – 35 U.S.C. § 112**

In response to the Examiner's 35 U.S.C. § 112 rejection, claims 4-7 and 13 have been cancelled and new claims 16-19 and 26-29 have been added. Moreover, kindly note that reference to sequence homology is frequently utilized in claim language. For example, enclosed herewith is U.S. Patent No. 6,558,937, which includes "at least 80% homology" in the claims. Since, in new claims 16-19 and 26-

29, the peptide in (b) now has the feature "at least about 80% homology" and "an action of promoting extension of bladder smooth muscle", the scope of these claims are clear.

### **Claims Rejection – 35 U.S.C. § 102**

The Examiner rejected previous claims 1-12 under 35 U.S.C. § 102(b) as being anticipated by Kitamura et al. (U.S. Patent No. 5,910,416). Specifically, the Examiner stated:

Claims 1-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Kitamura et al. (U.S. Patent 5,910,416). Kitamura et al. adrenomedullin as a novel hypotensive peptide. Kitamura et al. teach the intravenous administration of a composition comprising adrenomedullin (see figure 3; regarding claim 1). The composition of Kitamura et al. comprises the peptide having the amino acid sequence from Ser13 to TYR1 to TYR52, Ala(-73) to Tyr52, and Met(-94) to Leu91 of SEQ ID NO: 2 (regarding claims 4-7). In one embodiment of the above peptide, the carboxyl terminus of the peptide is amidated (see column 1, lines 66 and 67; regarding claim 8). In one embodiment of the above peptide, Gly is attached to the carboxyl terminus of the N-terminal peptide of proadrenomedullin (see column 2, lines 1 and 2). In one embodiment of the above peptide, Cys in the 16 position and Cys in the 21 position of SEQ ID NO: 1 are linked by a disulfide bond, which may be substituted with a –CH<sub>2</sub>-CH<sub>2</sub>- bond (see column 2, lines 8-13; regarding claims 10-12). Claims 2 and 3 further limit the use of the composition or the patient or disorder the composition is intended to treat and not the composition itself, and are thus included in this rejection as the claims are dependent on claim 1. Thus, the reference anticipates the invention as recited in claims 1-12.

However, please note that Kitamura et al. (U.S. Patent No. 5,910,416) describes adrenomedullin as a novel hypotensive peptide. Kitamura et al. does not teach or suggest an action of promoting passive extension of bladder smooth muscle or amelioration of urination disorders. Therefore, claims 13 and 15-34 are not anticipated by Kitamura et al.



CONCLUSION

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In view of the above amendments and comments, it is respectfully submitted that the presently pending claims are in condition for allowance. Early notification to that effect is respectfully requested.

Respectfully submitted,

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I hereby certify that this **Amendment** and **accompanying documents** are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" Service under 37 CFR 1.10 on the date indicated above and addressed to the Mail Stop Amendment Fee, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

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